



07-28-06
6,723,505 01

CofC #16

JUL 27 2006

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number

09/634,960

Filing Date

Aug. 08, 2000

First Named Inventor

Krank Karlsen

Art Unit

1634

Examiner Name

Jehanne Souaya

Attorney Docket Number

5775.018

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation of POA, Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	1. Transmittal Form (1 page);	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	2. Request for Certificate of Correction of Patent (4 pages);	
	3. Certificate of Correction (3 pages) in duplicate;	
	4. Copy of Amendment filed 01/14/2003, Exhibit A (19 pages) and Copy of Response, Exhibit B (1 page); and	
	5. Postcard.	

**Certificate
of Correction**
AUG 02 2006

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	DUNLAP, CODDING & ROGERS, P.C.		
Signature			
Printed name	Christopher W. Corbett		
Date	July 27, 2006	Reg. No.	36,109

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: *** SENT BY EXPRESS MAIL No. EL571032068US, DATED 07/27/06 ***

Signature			
Typed or printed name	Christopher W. Corbett	Date	July 27, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

AUG 2 2006

SPE RESPONSE FOR CERTIFICATE OF CORRECTION

DATE

: 9/26/06

Paper No.: _____

TO SPE OF : ART UNIT

1634

SUBJECT

: Request for Certificate of Correction on Patent No.:

6723505

A response is requested with respect to the accompanying request for a certificate of correction.

Please complete this form and return with file, within 7 days to:

Palm location **7580, Certificates of Correction Branch – South Tower – 9A22**

If response is for an IFW, return to employee (named below) via PUBSCofC Team in **MADRAS**.

With respect to the change(s) requested, correcting Office and/or Applicant's errors, should the patent read as shown in the certificate of correction (COCIN)? No new matter should be introduced, nor should the scope or meaning of the claims be changed.

Lamonte M. Newsome

Thank You For Your Assistance

Certificates of Correction Branch

Tel. No. 703-305-8309

The request for issuing the above-identified correction(s) is hereby:

Note your decision on the appropriate box.

☐ **Approved**

All changes apply.

☐ **Approved in Part**

Specify below which changes **do not** apply.

☐ **Denied**

State the reasons for denial below.

Comments:

SPE

Art Unit

EXPRESS MAIL NO.: EL 971032068 US
DATE DEPOSITED: July 27, 2006

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number: US 6,723,505 B1

Issued: Apr. 20, 2004

Name of Patentee: Frank Karlsen

Title of Invention: METHOD FOR IDENTIFICATION OF THE INDICATORS OF
CONTAMINATION IN LIQUID SAMPLES

Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450
Attention: Decision and Certificate of Correction
Branch of the Patent Issue Division

**REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT
FOR PTO AND/OR APPLICANT'S MISTAKES (37 CFR 1.322(a) and 1.323)**

Enclosed are:

- [X] 3 sheets of Form PTO-1050 (Amended), in duplicate, with at least one copy being suitable for printing.
- [X] Pre-addressed Postal Card

PTO ERRORS

The exact page and line number in the application file are:

The following errors were amended in an Amendment Under 37 CFR 1.312, filed 01/14/2003. Such Amendment was accepted by the Examiner on 03/11/2003. Attached as Exhibits A & B are copies of the Amendment and Response to Rule 312 Communication. However, changes requested in the 37 CFR 1.312 Amendment were not included when the patent was issued. Therefore, we respectfully request a Certificate of Correction for the following:

AUG 2 2006

Column 25, Line 10: After the word "of" and before the word "amplified" insert the word --said--. (See Amendment filed 01/14/03, pg. 15, Claim 6)

Column 25, Line 14: After the word "of" and before the word "amplified" insert the word --said--. (See Amendment filed 01/14/03, pg. 15, Claim 8)

Column 25, Line 17: After the word "E. Coli" insert the words --but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas species*, *Aeromonas hydrophila*, *Acinetobacter species*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia species*, and *Citrobacter freundii*--. (See Amendment filed 01/14/03, pg. 15-16, Claim 13)

Column 25, Line 26: After the word "E. Coli" insert the words --but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas species*, *Aeromonas hydrophila*, *Acinetobacter species*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia species*, and *Citrobacter freundii*--. (See Amendment filed 01/14/03, pg. 16-17, Claim 13)

Column 25, Line 38: After the word "detection" delete the word "reagent" and insert the word --agent--. (See Amendment filed 01/14/03, pg. 17, Claim 17)

Column 25, Line 42: After the word "detection" delete the word "reagent" and insert the word --agent--. (See Amendment filed 01/14/03, pg. 17, Claim 18)

Column 26, Line 1: After the word "of" and before the word "amplified" insert the word --said--. (See Amendment filed 01/14/03, pg. 18, Claim 26)

Column 26, Line 5: After the word "of" and before the word "amplified" insert the word --said--. (See Amendment filed 01/14/03, pg. 18, Claim 27)

Column 26, Line 18: After the word "of" and before the word "amplified" insert the word --said--. (See Amendment filed 01/14/03, pg. 18, Claim 28)

Column 26, Line 22: After the word "of" and before the word "amplified" insert the word --said--. (See Amendment filed 01/14/03, pg. 19, Claim 29)

Column 26, Line 32: After the word "detection" delete the word "reagent" and insert the word --agent--. (See Amendment filed 01/14/03, pg. 19, Claim 32)

Column 26, Line 36: After the word "detection" delete the word "reagent" and insert the word --agent--. (See Amendment filed 01/14/03, pg. 19, Claim 33)

Column 26, Line 46: After the word "detection" delete the word "reagent" and insert the word --agent--. (See Amendment filed 01/14/03, pg. 19, Claim 37)

Column 26, Line 50: After the word "detection" delete the word "reagent" and insert the word --agent--. (See Amendment filed 01/14/03, pg. 19, Claim 38)

☒ No fee is submitted herewith.

AUG 2 2006

APPLICANT'S ERRORS

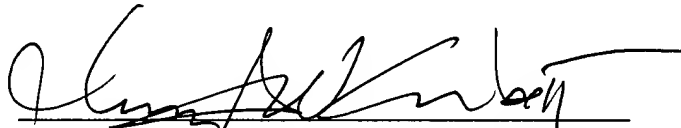
It is noted that errors appear in this patent of a clerical or typographical nature or a minor character as more fully described below. These errors occurred in good faith and correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination and a certificate of correction is requested.

The exact page and line number where the mistakes occur in the application are:

- [] Charge to credit card as shown on the attached credit card information authorization form PTO-2038, in the amount of \$100.00 for this Certificate of Correction. One copy of this sheet is attached.

RETURN OF CERTIFICATE

Please send the Certificate to the undersigned.



Christopher W. Corbett, Reg. No. 36,109
DUNLAP, CODDING & ROGERS, P.C.
P.O. Box 16370, Customer No. 30589
Oklahoma City, Oklahoma 73113
Telephone: 405/607-8600
Facsimile: 405/607-8686

Agent for Applicant

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO : 6,723,505 B1

Page 1 of 3 pages

DATED : 04/20/2004

INVENTOR(S) : Frank Karlsen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 25, Line 10: After the word "of" and before the word "amplified" insert the word --said--.

Column 25, Line 14: After the word "of" and before the word "amplified" insert the word --said--.

Column 25, Line 17: After the word "E. Coli" insert the words --but not Shigella boydii, Shigella flexneri, Salmonella typhi, Salmonella enterica, Salmonella arizonae, Enterobacter cloacae, Enterobacter aeromonas, Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Pseudomonas species, Aeromonas hydrophila, Acinetobacter species, Klebsiella pneumoniae, Listeria monocytogenes, Neisseria meningitidis, Campylobacter jejuni, Campylobacter coli, Erwinia species, and Citrobacter freundii--.

Column 25, Line 26: After the word "E. Coli" insert the words --but not Shigella boydii, Shigella flexneri, Salmonella typhi, Salmonella enterica, Salmonella arizonae, Enterobacter cloacae, Enterobacter aeromonas, Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Pseudomonas species, Aeromonas hydrophila, Acinetobacter species, Klebsiella pneumoniae, Listeria monocytogenes, Neisseria meningitidis, Campylobacter jejuni, Campylobacter coli, Erwinia species, and Citrobacter freundii--.

MAILING ADDRESS OF SENDER: Dunlap, Codding & Rogers, P.C.
P. O. Box 16370
Oklahoma City, Oklahoma 73113

PATENT NO. 6,723,505 B1

No. of additional copies

SEND TO: Mail Stop Patent Application, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

AUG 2 2006

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO : 6,723,505 B1



Page 2 of 3 pages

DATED : 04/20/2004

INVENTOR(S) : Frank Karlsen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 25, Line 38: After the word "detection" delete the word "reagent" and insert the word --agent--.

Column 25, Line 42: After the word "detection" delete the word "reagent" and insert the word --agent--.

Column 26, Line 1: After the word "of" and before the word "amplified" insert the word --said--.

Column 26, Line 5: After the word "of" and before the word "amplified" insert the word --said--.

Column 26, Line 18: After the word "of" and before the word "amplified" insert the word --said--.

Column 26, Line 22: After the word "of" and before the word "amplified" insert the word --said--.

Column 26, Line 32: After the word "detection" delete the word "reagent" and insert the word --agent--.

Column 26, Line 36: After the word "detection" delete the word "reagent" and insert the word --agent--.

MAILING ADDRESS OF SENDER: Dunlap, Coddling & Rogers, P.C.
P. O. Box 16370
Oklahoma City, Oklahoma 73113

PATENT NO. 6,723,505 B1



No. of additional copies

AUG 2 2006

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO : 6,723,505 B1



Page 3 of 3 pages

DATED : 04/20/2004

INVENTOR(S) : Frank Karlsen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 26, Line 46: After the word "detection" delete the word "reagent" and insert the word —agent—.

Column 26, Line 50: After the word "detection" delete the word "reagent" and insert the word —agent—.

MAILING ADDRESS OF SENDER: Dunlap, Coddling & Rogers, P.C.
P. O. Box 16370
Oklahoma City, Oklahoma 73113

PATENT NO. 6,723,505 B1

No. of additional copies

Express Mail No.: EV 262274420 US
Mailed: January 14, 2003



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Frank Karlsen

Dkt. No.: 5775.018

Serial No.: 09/634,960

Group Art Unit: 1634

Filed: August 8, 2000

Examiner: Jehanne E. Souaya

For: METHOD FOR IDENTIFICATION OF THE INDICATORS
OF CONTAMINATION IN LIQUID SAMPLES

Box AF Amendment
Commissioner for Patents
Washington, D.C. 20231

Amendment and Response Under 37 C.F.R. §1.116

In response to the Office action of October 15, 2002, please amend the
above-identified application as follows.

**Due to the indefinite suspension of U.S. Express Mail services and pursuant to the PTO instructions of 11/19/2001, the enclosed documents are being deposited for U.S. Express Mail in an envelope addressed to: BOX AF AMENDMENT COMMISSIONER FOR PATENTS, 2900 CRYSTAL DRIVE, ARLINGTON, VA 22202-3513. IT IS OUR UNDERSTANDING THE PTO WILL BE RESPONSIBLE FOR FORWARDING ALL OF THE ENCLOSED DOCS. TO THE PTO OFFICE LOCATED IN WASHINGTON D.C.

AUG 2 2006

In the Claims:

Please amend claims 6, 8, 13, 17, 18, 26-29, 32-33, and 37-38, which are submitted herewith in clean, replacement form as follows. Also, submitted herein below following the Remarks section are redlined, marked up versions of claims 6, 8, 13, 17, 18, 26-29, 32-33, which illustrate the amendments made to such claims.

Clean Version of Replacement Claims:

6. (Twice Amended) A method of specifically detecting *E. coli* in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;
recovering bacteria from the liquid or liquified sample;
lysing the bacteria to provide a DNA sample;
treating the DNA sample under PCR conditions with a primer set specific for *E. coli* for forming an amplified DNA wherein the primer set comprises SEQ ID NO:1 and SEQ ID NO:14; and
detecting the presence of said amplified DNA as an indication of the presence of *E. coli* in the liquid or liquified sample.

8. (Twice Amended) The method of claim 6 wherein in the step of detecting the presence of said amplified DNA, the presence of *Escherichia coli*

is indicated when a signal is obtained which exceeds a predetermined threshold.

13. (Three-times Amended) A method of specifically detecting *E. coli* but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas* species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii* in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

selecting a target gene of *E. coli* and selecting an *E. coli*-specific

target DNA sequence in the target gene;

incubating the DNA sample under amplification conditions with a

DNA polymerase and a primer pair specific for *E. coli* but not

Shigella boydii, *Shigella flexneri*, *Salmonella typhi*,

Salmonella enterica, *Salmonella arizonae*, *Enterobacter*

cloacae, *Enterobacter aeromonas*, *Enterococcus faecalis*,

Enterococcus faecium, *Streptococcus pyogenes*,

Pseudomonas species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii* for amplifying the target DNA sequence; and

detecting the presence of amplified DNA as a specific indication of the presence of *E. coli* carrying the selected *E. coli*-specific target DNA sequence, wherein the target gene is the *lamB* gene of *Escherichia coli*.

17. (Twice Amended) The kit of claim 16 wherein the detection agent is a dsDNA stain.

18. (Twice Amended) The kit of claim 16 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection agent.

26. (Once Amended) A method of specifically detecting *E. coli* in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;
treating the DNA sample under PCR conditions with a primer set
specific for *E. coli* for forming an amplified DNA wherein the
primer set comprises SEQ ID NO:2 and SEQ ID NO:15; and
detecting the presence of said amplified DNA as an indication of the
presence of *E. coli* in the liquid or liquified sample.

27. (Once Amended) The method of claim 26 wherein in the step of
detecting the presence of said amplified DNA, the presence of *Escherichia coli*
is indicated when a signal is obtained which exceeds a predetermined threshold.

28. (Once Amended) A method of specifically detecting *E. coli* in a liquid
or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;
recovering bacteria from the liquid or liquified sample;
lysing the bacteria to provide a DNA sample;
treating the DNA sample under PCR conditions with a primer set
specific for *E. coli* forming an amplified DNA wherein the
primer set comprises SEQ ID No:3 and SEQ ID NO:16; and
detecting the presence of said amplified DNA as an indication of the
presence of *E. coli* in the liquid or liquified sample.

29. (Once Amended) The method of claim 28 wherein in the step of detecting the presence of said amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

32. (Once Amended) The kit of claim 31 wherein the detection agent is a dsDNA stain.

33. (Once Amended) The kit of claim 31 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection agent.

37. (Once Amended) The kit of claim 36 wherein the detection agent is a dsDNA stain.

38. (Once Amended) The kit of claim 36 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection agent.

AUG 2 2006

Remarks

This is intended to be a complete response to the official action mailed October 15, 2002 in which claims 6, 8, 13, 17, 18, 26-29, 32, 33, 37 and 38 were rejected and claims 1-3, 14, 16, 19, 30, 31, 34-36 and 39 were allowed in a final action.

Applicant respectfully requests entry of the amendments made herein under 37 CFR §1.116 in view of the fact that said amendments cause the rejections to be overcome, and in view of the fact that the amendments have been made in accordance with the examiner's suggestions.

First Rejection Under § 112 ¶2

Claims 17 and 18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the rejection it is stated:

"Claims 17 and 18 recite the limitation "the detection reagent" in lines 1 and 3 respectively. There is insufficient antecedent basis for this limitation in the claim."

Claims 17 and 18 have been amended to replace "reagent" with "agent", which has antecedent basis in claim 16, which claims 17 and 18 depend from.

In view of the amendments to claims 17 and 18, applicant respectfully requests reconsideration and withdrawal of the rejection under §112 ¶2.

Second Rejection Under §112 ¶2

Claims 6, 8, 26-29, 32-33, 37 and 38 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the rejection it is stated:

"Claims 32 and 33 (and claims 37 and 38) recite the limitation "the detection reagent" in lines 1 and 3 respectively. There is insufficient antecedent basis for this limitation in the claim."

Claims 32, 33, 37 and 38 have been amended in a manner similar to the amendments of claims 17 and 18. In view of the amendments, applicant respectfully requests reconsideration and withdrawal of the rejection.

In the rejection it was also stated:

"Claims 6 and 8 (and claims 26 and 27, 28 and 29) are unclear in the recitation of "amplified DNA" in lines 15 and 2 respectively, because it is unclear what "amplified DNA" is being referred to. For example, does the term refer to "forming an amplified DNA" in line 9 of claim 6, or to other amplified DNA? This rejection can be easily overcome by reciting instead "said amplified DNA" in lines 15 and 2 of claims 6 and 8 (26 and 27, 28 and 29) respectively."

Claims 6, 8 and 26-29 have been amended in accordance with the examiner's suggestion to further identify the secondly recited "amplified DNA" as "said amplified DNA" to correct the antecedent basis of the term.

In view of the above, applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under §112 ¶2.

Rejection Under §102(b)

Claim 13 stands rejected under 35 U.S.C. 102(b) as being anticipated by Atlas et al. (US Patent 5,298,392; 3/29/194).

In the rejection it is stated:

"Absent a precise definition as to what is meant by "specifically detecting E. Coli", the recitation has been broadly interpreted to encompass "particularly or especially the detection of E. Coli", which is taught by Atlas et al. As the claim does not recite definite bacterial species that would not be detected by the method, the recitation of "specifically detecting E. Coli" or "specific for E. Coli" in instantly pending claim 13 is not sufficient to distinguish the method of claim 13 over the teachings of Atlas et al. It is noted that this rejection can be overcome by amending the claim to explicitly recite "specifically detecting E. Coli but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas* species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii* (as recited on pages 19 and 20 of the specification)."

Claim 13 has been amended in accordance with the examiner's suggestion to indicate that the method detects E. coli but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas species*, *Aeromonas hydrophila*, *Acinetobacter species*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia species*, and *Citrobacter freundii* . The amendment is supported on pages 19-20 of the specification.

In view of the above, applicant respectfully submits the claim is now allowable over the cited art and respectfully requests reconsideration and withdrawal of the rejection under §102(b) over Atlas et al.

Priority

In the official action it was stated:

"The response traverses the examiner's indication that SEQ ID NOS 2, 3, 15, and 16 are not due the benefit of the priority date of the provisional application 60/149,365 (August 13, 1999) on the grounds that the statement at page 23, lines 7-11, of the '365 application" "primer pair is selected from the group consisting of primer sequences comprising a substantial part of SEQ ID No 1 and SEQ ID NO 2..." supports SEQ ID NOS 2, 3, 15, and 16 of the instant application because SEQ ID NOS 2 and 3, and SEQ ID NOS 15, and 16 comprise a "substantial part" of SEQ ID NO 1 (identical in '365 and the instant application)

and SEQ ID NO 2 (identical to SEQ ID NO 14 in the instant application) respectively. This argument has been thoroughly reviewed but was not found persuasive because sequences *consisting* of the specific nucleotide sequences of SEQ ID NO 2, 3, 15, and 16 were not disclosed in the provisional application, nor did the provisional application make clear what constituted a "substantial part" of SEQ ID NOS 1 and 2."

Although the issue of priority of SEQ ID NOS 2, 3, 15, and 16 does not presently bear on the allowability of the pending claims, applicant continues to traverse examiner's assertion that said sequences are not due the benefit of the priority date of the provisional application. The issue of priority rests on the meaning and interpretation of "substantial".

The courts have, on numerous occasions, addressed the use and meaning of the terms "substantial" or "substantially".

For example, in *York Products, Inc. V. Central Tractor Farm & Family*, 99 F.3d 1568, 1572-1573, 40 USPQ2d 1619 (U.S.C.A. Fed. Cir. 1996) (provided herein as Attachment 1), the court held that "substantially" ordinarily meant "considerable in...extent," (quoting *American Heritage Dictionary Second College Edition* 1213 (2d ed. 1982)), or "largely but not wholly that which is specified," (quoting *Webster's Ninth New Collegiate Dictionary* 1176 (9th ed. 1983)).

Moreover, in *Ecolab*, the Court of Appeals for the Federal Circuit referred to *Andrew Corp. V. Gabriel Elecs. Inc.*, 847 F.2d 819, 821-822, 6 USPQ2d 2010, 1013 (Fed Cir. 1988) (provided herein as Attachment 2) in stating:

that terms such as "approach each other," "close to," "substantially equal," and "closely approximate" are ubiquitously used in patent claims and that such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claims subject matter from the prior art, have been accepted in patent examination and upheld by the courts.

If one follows the reasoning of the Federal Circuit in *York Products*, i.e., the "substantial" means "largely but not wholly that which is specified", one would then reasonably conclude that a "substantial part" of SEQ ID NO 1 or SEQ ID NO 2 [now SEQ ID NO 14] would be a "large but not whole" part of SEQ ID NO 1 or SEQ ID NO 2 [now SEQ ID NO 14].

It can be readily seen from Table V and from the Sequence Listing of the present specification that present SEQ ID NOS 2 and 3 each comprise 23 of the 24 nucleotides of SEQ ID NO 1. Likewise SEQ ID NOS 15 and 16 each comprise 23 of the 24 nucleotides of SEQ ID NO 14.

Given the definition of "substantial" sanctioned by the Federal Circuit ("largely but not wholly that which is specified"), it is evident that SEQ ID NOS 2 and 3 are "substantial parts" of SEQ ID NO 1, and SEQ ID NOS 15 and 16 are

"substantial parts" of SEQ ID NO 14, regardless of whether or not they are explicitly described in the provisional application. They are inherently described in the provisional application as "substantial parts" of the entire 24-base sequence.

Applicant therefore respectfully submits SEQ ID NOS 2, 3, 15 and 16 are therefore due the benefit of the priority date of the provisional application, U.S. Serial No. 60/149,365.

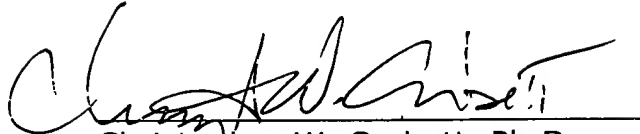
Conclusion

In view of the above, applicant respectfully submits the claims are in a condition for allowance and requests issuance of a Notice of Allowance therefore.

Marked Up Version of the Claims

Attached hereto is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Christopher W. Corbett", written over a horizontal line.

Christopher W. Corbett, Ph.D.

Reg. No. 36,109

DUNLAP, CODDING & ROGERS, P.C.

P.O. Box 16370

Oklahoma City, OK 73113

Customer No.: 30589

Telephone: (405) 478-5344

Facsimile: (405) 478-5349

Agent for Applicant

AUG 2 2006

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

6. (Twice Amended) A method of specifically detecting E. coli in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

treating the DNA sample under PCR conditions with a primer set

specific for E. coli for forming an amplified DNA wherein the

primer set comprises SEQ ID NO:1 and SEQ ID NO:14; and

detecting the presence of **said** amplified DNA as an indication

of the presence of E. coli in the liquid or liquified sample.

8. (Twice Amended) The method of claim 6 wherein in the step of detecting the presence of **said** amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

13. (Three-times Amended) A method of specifically detecting E. coli **but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter***

AUG 2 2006

aeromonas, *Enterococcus faecalis*, *Enterococcus faecium*,
Streptococcus pyogenes, *Pseudomonas* species, *Aeromonas hydrophila*,
Acinetobacter species, *Klebsiella pneumoniae*, *Listeria monocytogenes*,
Neisseria meningitidis, *Campylobacter jejuni*, *Campylobacter coli*,
Erwinia species, and *Citrobacter freundii* in a liquid or liquified sample by
polymerase chain reaction, comprising:

providing a liquid or liquified sample;
recovering bacteria from the liquid or liquified sample;
lysing the bacteria to provide a DNA sample;
selecting a target gene of *E. coli* and selecting an *E. coli*-specific
target DNA sequence in the target gene;
incubating the DNA sample under amplification conditions with a
DNA polymerase and a primer pair specific for *E. coli* **but not**
Shigella boydii, *Shigella flexneri*, *Salmonella typhi*,
Salmonella enterica, *Salmonella arizonae*, *Enterobacter*
cloacae, *Enterobacter aeromonas*, *Enterococcus*
faecalis, *Enterococcus faecium*, *Streptococcus*
pyogenes, *Pseudomonas* species, *Aeromonas*
hydrophila, *Acinetobacter* species, *Klebsiella*
pneumoniae, *Listeria monocytogenes*, *Neisseria*
meningitidis, *Campylobacter jejuni*, *Campylobacter*

coli, *Erwinia* species, and *Citrobacter freundii* for

amplifying the target DNA sequence; and

detecting the presence of amplified DNA as a specific indication of the presence of *E. coli* carrying the selected *E. coli*-specific target DNA sequence, wherein the target gene is the *lamB* gene of *Escherichia coli*.

17. (Twice Amended) The kit of claim 16 wherein the detection **[reagent] agent** is a dsDNA stain.

18. (Twice Amended) The kit of claim 16 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection **[reagent] agent**.

26. (Once Amended) A method of specifically detecting *E. coli* in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;

recovering bacteria from the liquid or liquified sample;

lysing the bacteria to provide a DNA sample;

treating the DNA sample under PCR conditions with a primer set specific for *E. coli* for forming an amplified DNA wherein the

primer set comprises SEQ ID NO:2 and SEQ ID NO:15; and detecting the presence of **said** amplified DNA as an indication of the presence of E. coli in the liquid or liquified sample.

27. (Once Amended) The method of claim 26 wherein in the step of detecting the presence of **said** amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

28. (Once Amended) A method of specifically detecting E. coli in a liquid or liquified sample by polymerase chain reaction, comprising:

providing a liquid or liquified sample;
recovering bacteria from the liquid or liquified sample;
lysing the bacteria to provide a DNA sample;
treating the DNA sample under PCR conditions with a primer set specific for E. coli forming an amplified DNA wherein the primer set comprises SEQ ID No:3 and SEQ ID NO:16; and detecting the presence of **said** amplified DNA as an indication of the presence of E. coli in the liquid or liquified sample.

29. (Once Amended) The method of claim 28 wherein in the step of detecting the presence of **said** amplified DNA, the presence of *Escherichia coli* is indicated when a signal is obtained which exceeds a predetermined threshold.

32. (Once Amended) The kit of claim 31 wherein the detection **[reagent] agent** is a dsDNA stain.

33. (Once Amended) The kit of claim 31 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection **[reagent] agent**.

37. (Once Amended) The kit of claim 36 wherein the detection **[reagent] agent** is a dsDNA stain.

38. (Once Amended) The kit of claim 36 further comprising a detection well having streptavidin coated thereon wherein the amplified DNA sequence is detected by the detection **[reagent] agent**.

AUG 2 2006

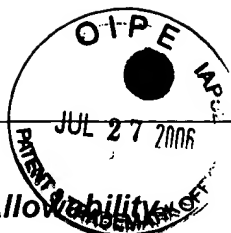


EXHIBIT B

Notice of Allowability

Application No.

09/634,960

Examiner

Jehanne E Souaya

Applicant(s)

KARLSEN, FRANK

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. [X] This communication is responsive to the proposed amendment filed January 14, 2003.
2. [X] The allowed claim(s) is/are 1-3,6,8,13,14,16-19 and 26-39.
3. [] The drawings filed on _____ are accepted by the Examiner.
4. [] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
5. [X] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
6. [] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 7. [] A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. [] CORRECTED DRAWINGS must be submitted.
(a) [] including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
(b) [] including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
(c) [] including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

- 9. [] DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1 [] Notice of References Cited (PTO-892)
2 [] Notice of Informal Patent Application (PTO-152)
3 [] Notice of Draftsperson's Patent Drawing Review (PTO-948)
4 [X] Interview Summary (PTO-413), Paper No. _____.
5 [] Information Disclosure Statements (PTO-1449), Paper No. _____.
6 [X] Examiner's Amendment/Comment
7 [] Examiner's Comment Regarding Requirement for Deposit of Biological Material
8 [X] Examiner's Statement of Reasons for Allowance
9 [] Other

AUG 2 2006

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO : 6,723,505 B1

Page 1 of 3 pages

DATED : 04/20/2004

INVENTOR(S) : Frank Karlisen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 25, Line 10: After the word "of" and before the word "amplified" insert the word —said—.

Column 25, Line 14: After the word "of" and before the word "amplified" insert the word —said—.

Column 25, Line 17: After the word "E. Coli" insert the words —but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas species*, *Aeromonas hydrophila*, *Acinetobacter species*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia species*, and *Citrobacter freundii*—.

Column 25, Line 26: After the word "E. Coli" insert the words —but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas species*, *Aeromonas hydrophila*, *Acinetobacter species*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia species*, and *Citrobacter freundii*—.

MAILING ADDRESS OF SENDER: Dunlap, Codding & Rogers, P.C.
P. O. Box 16370
Oklahoma City, Oklahoma 73113

PATENT NO. 6,723,505 B1

No. of additional copies

SEND TO: Mail Stop Patent Application, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

AUG 2 2004

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO : 6,723,505 B1

Page 2 of 3 pages

DATED : 04/20/2004

INVENTOR(S) : Frank Karlsen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 25, Line 38: After the word "detection" delete the word "reagent" and insert the word —agent—.

Column 25, Line 42: After the word "detection" delete the word "reagent" and insert the word —agent—.

Column 26, Line 1: After the word "of" and before the word "amplified" insert the word —said—.

Column 26, Line 5: After the word "of" and before the word "amplified" insert the word —said—.

Column 26, Line 18: After the word "of" and before the word "amplified" insert the word —said—.

Column 26, Line 22: After the word "of" and before the word "amplified" insert the word —said—.

Column 26, Line 32: After the word "detection" delete the word "reagent" and insert the word —agent—.

Column 26, Line 36: After the word "detection" delete the word "reagent" and insert the word —agent—.

MAILING ADDRESS OF SENDER: Dunlap, Coddling & Rogers, P.C.
P. O. Box 16370
Oklahoma City, Oklahoma 73113

PATENT NO. 6,723,505 B1

No. of additional copies

APR 2, 2006

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

PATENT NO : 6,723,505 B1



Page 3 of 3 pages

DATED : 04/20/2004

INVENTOR(S) : Frank Karlsen

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 26, Line 46: After the word "detection" delete the word "reagent" and insert the word --agent--.

Column 26, Line 50: After the word "detection" delete the word "reagent" and insert the word --agent--.

MAILING ADDRESS OF SENDER: Dunlap, Coddling & Rogers, P.C.
P. O. Box 16370
Oklahoma City, Oklahoma 73113

PATENT NO. 6,723,505 B1 ■

No. of additional copies

APR 2 2004